K062809
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510(k) Summary
per of 21 C.F.R § 807.92

Manufacturer's Name and Address	Invatec Innovative Technologies Via Martiri della Libertà, 7 25030 Roncadelle (BS) Italy Tel: +39 030 258 93 11 Fax: +39 030 258 93 12 www. invatec.com info@invatec.com
Submitter's Name and Address	ev3 Inc. 4600 Nathan Lane North Plymouth, MN 55442 Tel: (763) 398 7000 Fax: (763) 398 7200
Contact Person	David Worrell Manager, Regulatory Affairs Tel: (763) 398-7344 Fax: (763) 398-7200 e-mail: dworrell@ev3.net
Date Prepared	September 18, 2006
Device Trade Name	ADMIRAL XTREME™ Percutaneous Transluminal Angioplasty (PTA) Catheter
Device Common Name	Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter
Classification Name	21 CFR 870.1250 Percutaneous Catheter
Device Classification	Regulatory Class: Class II Product Code: LIT
Classification Panel	Cardiovascular
Predicate Device	SAILOR PLUS™ Percutaneous Transluminal Angioplasty (PTA) Catheter – K042538, cleared November 8, 2004
Intended use	The ADMIRAL XTREME™ (PTA) Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Device Description	The ADMIRAL XTREME™ PTA Catheter is an OTW PTA catheter with a semi-compliant inflatable balloon mounted at the distal tip. It is a dual lumen catheter with a guidewire lumen and a balloon inflation lumen. The catheter tapers beneath the balloon segment to achieve the lowest possible deflated profile. Two radiopaque marker bands are placed under the balloon segment of the catheter shaft to provide visual reference points for balloon positioning within the vessel. The distal catheter shaft and balloon cones are hydrophilic coated (balloon excluded). The maximum recommended guidewire diameter is 0.035". The device is available in balloon diameters of 3-12mm, balloon lengths of 20, 40, 60, 80 and 120mm and catheter lengths of 80 and 130cm.
Biocompatibility	All materials used in the ADMIRAL XTREME™ PTA Catheter are

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	biocompatible based on biocompatibility testing results.
Performance data	In vitro testing was conducted to demonstrate equivalent performance of the ADMIRAL XTREME™ Percutaneous Transluminal Angioplasty (PTA) Catheter with the predicate device. The testing included balloon compliance, balloon burst pressure, balloon fatigue, shaft burst pressure, bond strength, catheter dimensions, deflation time and guidewire and introducer compatibility.
Summary of Substantial Equivalence	The ADMIRAL XTREME™ Percutaneous Transluminal Angioplasty (PTA) Catheter is identical to the predicate device with respect to intended use, catheter design and balloon dimensions. The mechanical and biocompatibility testing data met the specified requirements for the ADMIRAL XTREME™ Percutaneous Transluminal Angioplasty (PTA) Catheter and are comparable with the predicate device.
Conclusion	Based on the intended use and the technological characteristics, the ADMIRAL XTREME™ PTA Catheter has been shown to be substantially equivalent to the SAILOR PLUS™ PTA Catheter (K0402538, cleared November 8, 2004).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Invatec Innovative Technologies
c/o ev3 Inc.
Attn: David Worrell
9600 54th Avenue North
Plymouth, MN 55442-2111

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Re: K062809
Trade/Device Name: ADMIRAL XTREME™ PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 18, 2006
Received: September 19, 2006

Dear Mr. Worrell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K062809

Device Name: **ADMIRAL XTREME™ PTA Catheter**

Indications for Use:

The ADMIRAL XTREME™ PTA Balloon Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna R. Barlow

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062809